**REMARKS**

Claims 88-105 are currently pending in the subject application. Applicant has not hereinabove added, amended or cancelled any claims.

**Rejection Under 35 U.S.C. §112, Written Description**

The Examiner rejected claims 89-105 as allegedly containing subject matter not described in the specification so as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner states that the application has a single example of a tablet which contains, inter alia, 2.5mg oxandrolone. The Examiner further stated that the "application merely mentions 10-milligram dosage, but does not disclose further information as to the carrier and particular forms."

The Examiner also asserted that it is well settled that a broad and general disclosure of a genus would not support a species encompassed by the genus.

In response, applicant respectfully traverses the Examiner's rejection. As noted in the previous Office Action, the specification at page 5, lines 19-22 does in fact support the "unit dosage form" of the claimed composition. The specification states that "...in accordance with this invention, the active ingredient oxandrolone is combined with solid or liquid pharmaceutical carriers and formulated in unit dosage form..." Furthermore, lines 27-30 note that the dose can be "as low as about" 2.5 mg and "as high as about" 20mg. Page 4, line 4 recites that a dose used in the study was a 10mg dose.

Applicant did disclose as to the particular forms which included oral, percutaneous, transdermal, sublingual, buccal, intravenous, intramuscular, or the like (see specification, p. 6, lines 29-32).

Furthermore, Applicant does not disagree with the Examiner's position that a broad and general disclosure of a genus alone might not support a species encompassed by the genus. However, applicants respectfully traverse the current rejection on the fact that that this is not the situation in the present invention, because the use of a 10 mg tablet, as well as various other dosages, were clearly disclosed throughout the specification, as was the carrier and particular forms. Moreover, disclosure of a species can clearly support a claim to that species as in the present case.

Applicant further notes that the written description standard requires that the specification "reasonably convey to one skilled in the art that the inventor(s) at the time the application was filed, had possession of the claimed invention." It is not a reasonable position that one skilled in the art would not recognize applicant to be in possession of the invention as claimed, especially in light of the disclosures on pages 4 and 5 as noted hereinabove.

Applicant submits that the invention recited in the pending claims is fully described in the subject application. Accordingly, Applicant respectfully requests reconsideration and withdrawal of this ground of rejection.

**Rejection Under 35 U.S.C. §103(a)**

The Examiner rejected claims 88-105 under 35 U.S.C. §103(a) as allegedly obvious over Metcalf et al. (of record) in view of ANAVAR® (of record) and Babu et al. (U.S. Patent No. 5,073,380) and "further in view of applicants' admission at page 7." The Examiner alleged, inter alia, that it would have been prima facie obvious to one of ordinary skill in the art to make a dosage composition comprising 10mg oxandrolone with particular excipients, and that 10mg would have been obvious in view of the "the fact that it [would] have been used in the amount of 10mg, 20mg, and up to 150mg." The Examiner alleged that "one of ordinary skill in the art would have been motivated to make a tablet with 10 mg of oxandrolone for those uses of more than 10 mg a day."

The Examiner further claimed that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning, but so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper.

Lastly, the Examiner asserted that the "pill-burden" issues presented in the last Office Action are not sufficient to rebut the prima facie case of obviousness as a mere change in size or shape of subject matter would not make the subject matter patentably distinguishable.

*Applicant's response*

In response, applicant respectfully traverses the Examiner's rejection.

Different Regimen

The Examiner has dismissed art-recognized pill burden issues with the idea that a 10 mg dose provides patients "with more options." In response, quite apart from the fact the pill-burden is an art-recognized issue, and the fact that the Examiner has presented a new theory without any cited support, by the Examiner's reasoning a 1 mg dose would presumably be the obvious choice, not 10 mg, as a 1 mg dose provides patients with even more options. In any event, patient compliance is a problem of which those in the art are aware, and suggests against a 10 mg unit dose form as being obvious. The Examiner has not addressed this. Moreover, the Examiner still has not addressed why selection of a 10 mg dose, out of all the possible integer doses between, e.g., 1 mg and 30 mg, would be obvious.

Applicant's Invention Teaches Away from Prior Art

Applicant further notes that due to the art-recognized problems of (1) patient compliance and (2) pill-burden, a *three* times a day regimen as suggested by the Examiner is not an obvious choice. In fact, pill-burden argues *against* the Examiner's selection of the three times per day regimen. Applicants understand that a change in size and shape of subject matter would not make the subject matter patentably distinguishable. However, the Applicants invention differs in more than size and shape. Accordingly, there is a change in the regimen making it more burdensome for a patient to take the pill. The prior art is clearly trying to make it easier for patients and decrease pill burden. In fact, Babu et al., states

> [i]t is desirable to extend the dosing interval of many pharmaceuticals while maintaining the initial Plasma concentrations achievable with conventional tablets or caplets. This would provide immediate and extended therapeutic effect and reduce the number of doses necessary,

> thereby making therapy more convenient. A way to do this hw now been found using the present invention (see page 2).

Applicant's invention would be teaching away from this prior art because a three times a day regimen is actually doing the opposite and not extending the dosing interval to provide extending therapeutic relief.

In addition, Applicant respectfully reminds the Examiner that Metcalf explicitly teaches that the optimal combined daily amount is 25-30mg per day (see Metcalf, p 63) and discuss the "variable response at low dose levels" (see Metcalf, p60). Applicant maintains that one of ordinary skill in the art would therefore not be motivated to produce a 10mg unit dosage form based on Metcalf's express teaching that such a low dose is not useful.

Applicant maintains that the invention as claimed is not obvious over the cited combination of prior art and accordingly, applicant respectfully requests reconsideration and withdrawal of this ground of rejection.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicant's undersigned attorneys invite the Examiner to telephone them at the number provided below.

No fee, is deemed necessary with the filing of this Communication. However, if any additional fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,

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